

MAY 15 1998

Sally L. Van Wert, Ph.D.
Manager, Regulatory Affairs - Biotechnology
AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

Dear Dr. Van Wert:

This is in regard to AgrEvo's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its glufosinate-tolerant soybean lines A2704-12 and A5547-127. According to AgrEvo, the new soybean varieties have been rendered tolerant to glufosinate ammonium herbicides through expression of a modified phosphinothricin acetyltransferase (*pat*) gene from *Streptomyces viridochromogenes*.

As part of bringing the consultation regarding these varieties to closure, you submitted a summary safety and nutritional assessment of the genetically modified soybean varieties on March 31, 1998. This communication informed FDA of the steps taken by AgrEvo to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment AgrEvo has conducted, it is our understanding that AgrEvo has concluded that the new soybean varieties are not materially different in composition, safety, or any other relevant parameters from soybean lines currently on the market and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0055 that will be maintained in the Office of Premarket Approval.

Based on the information AgrEvo has presented, we have no further questions concerning these new soybean varieties at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/s/

Alan M. Rulis, Ph.D.

Director

Office of Premarket Approval

Center for Food Safety

and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246 HFS-247
HFS-13 HFV-200 BNF0055